

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Piergiorgio DONATI, et al.

J005136/PCT/PTO 19 SEP 2005

SERIAL NO: New U.S. PCT Application Based on PCT/EP04/50286

GAU:

FILED: Herewith

EXAMINER:

FOR: LIQUID GROWTH HORMONE FORMULATION AND PROCESS OF PREPARATION THEREOF

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

REFERENCES

- ☒ The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

RELATED CASES

- ☐ Attached is a list of applicant's pending application(s), published application(s) or issued patent(s) which may be related to the present application. In accordance with the waiver of 37 CFR 1.98 dated September 21, 2004, copies of the cited pending applications are not provided. Cited published and/or issued patents, if any, are listed on the attached PTO form 1449.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

CERTIFICATION

- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

DEPOSIT ACCOUNT

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.



Norman F. Oblon

Registration No. 24,618

Customer Number

22850

Tel. (703) 413-3000  
Fax. (703) 413-2220  
(OSMMN 05/03)

Surinder Sachar

Registration No. 34,423

10/549763

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Piergiorgio DONATI, et al.

SERIAL NO: New U.S. PCT Application Based on PCT/EP04/50286

GAU:

FILED: Herewith

EXAMINER:

FOR: LIQUID GROWTH HORMONE FORMULATION AND PROCESS OF PREPARATION THEREOF

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

REFERENCES

- ☒ The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

RELATED CASES

- ☐ Attached is a list of applicant's pending application(s), published application(s) or issued patent(s) which may be related to the present application. In accordance with the waiver of 37 CFR 1.98 dated September 21, 2004, copies of the cited pending applications are not provided. Cited published and/or issued patents, if any, are listed on the attached PTO form 1449.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

CERTIFICATION

- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

DEPOSIT ACCOUNT

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.



Norman F. Oblon

Registration No. 24,618

Customer Number

22850

Tel. (703) 413-3000  
Fax. (703) 413-2220  
(OSMMN 05/03)

Surinder Sachar

Registration No. 34,423

|  |    |   |          |   |                       |   |                               |
|--|----|---|----------|---|-----------------------|---|-------------------------------|
| Form PTO 1449<br>(Modified)  |    | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE  |          | ATTY DOCKET NO.<br>277219US0PCT         |                       | SERIAL NO.<br>New U.S. PCT Application<br>Based on PCT/EP04/50286<br><b>10/549763</b> |                               |
| LIST OF REFERENCES CITED BY APPLICANT  |    |   |          | APPLICANT<br>Piergiorgio DONATI, et al. |                       | FILING DATE<br>Herewith   |                               |
|  |    |   |          | GROUP                                   |                       |   |                               |
| U.S. PATENT DOCUMENTS  |    |   |          |   |                       |   |                               |
| EXAMINER<br>INITIAL  |    | DOCUMENT<br>NUMBER  | DATE     | NAME                                    | CLASS                 | SUR<br>CLASS  | FILING DATE<br>IF APPROPRIATE |
|  | AA | 5,567,677   | 10/22/96 | CASTENSSON, Staffan et al.              |                       |   |                               |
| FOREIGN PATENT DOCUMENTS   |    |   |          |   |                       |   |                               |
|  |    | DOCUMENT<br>NUMBER  | DATE     | COUNTRY                                 | TRANSLATION<br>YES NO |   |                               |
|  | AB | 97/29767  | 08/21/97 | WO                                      |                       |   | NO                            |
|  | AC | 0 211 601   | 02/25/87 | EP                                      |                       |   | NO                            |
|  | AD | 93/19776  | 10/14/93 | WO                                      |                       |   | NO                            |
|  | AE | 94/03198  | 02/17/94 | WO                                      |                       |   | NO                            |
|  | AE | 0 131 864   | 01/23/85 | EP                                      |                       |   | NO                            |
| OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)  |    |   |          |   |                       |   |                               |
|  | AG | Stephen F. ALTSCHUL et al., "Basic Local Alignment Search Tool", J. Mol. Biol., Vol. 215, pages 403-410, 1990.  |          |   |                       |   |                               |
|  | AH | Stephen F. ALTSCHUL et al., "Gapped BLAST and PSI-BLAST: a new generation of protein database search programs", Nucleic Acids Research, Vol. 25, No. 17, pages 3389-3402, 1997.   |          |   |                       |   |                               |
|  | AI | Gerald W. BECKER et al., "Isolation and Characterization of a Sulfoxide and Desamido Derivative and Biosynthetic Human Growth Hormone", Biotechnology and Applied Biochemistry, Vol. 10, pages 326-337, 1988.                   |          |   |                       |   |                               |
|  | AJ | Thomas A. BEWLY et al., "Sequence comparison of human pituitary growth hormone, human chorionic somatomotropin, and ovine pituitary growth and lactogenic hormones", Int. J. Peptide Protein Res., Vol. 4, pages 281-287, 1972. |          |   |                       |   |                               |
|  | AK | Elison Y. CHEN et al., "The Human Growth Hormone Locus: Nucleotide Sequence, Biology, and Evolution", GENOMICS, Vol. 4, pages 479-497, 1989.  |          |   |                       |   |                               |
|  | AJ | John DEVEREUX et al., "A comprehensive set of sequence analysis programs for the VAX", Nucleic Acids Research, Vol. 12, No. 1, pages 387-395, 1984.   |          |   |                       |   |                               |
|  | AM | Arieh GERTLER et al., "Inhibition of Lactogenic Activities of Ovine Prolactin and Human Growth Hormone (hGH) by a Novel Form of a Modified Recombinant hGH" Endocrinology, Vol. 118, No. 2, pages 720-726, 1986.                |          |   |                       |   |                               |
|  | AN | David V. GOEDEL et al., "Direct expression in Escherichia coli of a DNA sequence coding for human growth hormone", Nature, Vol. 281, pages 544-548, October 18, 1979.   |          |   |                       |   |                               |
|  | AO | Laszlo GRAFF et al., "Human Somatotropin", The Journal of Biological Chemistry, Vol. 257, No. 5, pages 2356-2369, 1982.   |          |   |                       |   |                               |
|  | AP | GRANTHAM: "Amino Acid Difference Formula to Help Explain Protein Evolution", Science, Vol. 185, pages 862-864, 1974.  |          |   |                       |   |                               |
|  | AQ | Hansen M. HSIUNG et al., "Use of bacteriocin release protein in E. Coli for excretion of human growth hormone into the culture medium", Bio/Technology, Vol. 7, pages 267-271, March 1989.                                      |          |   |                       |   |                               |
|  | AR | Karin Damm JORGENSEN et al., "Pharmacokinetics of Biosynthetic and Pituitary Human Growth Hormones in Rats", Pharmacology & Toxicology, Vol. 63, pages 129-134, 1988.   |          |   |                       |   |                               |
|  | AS | U. J. LEWIS et al., "Enhancement of the Hyperglycemic Activity of Human Growth Hormone by Enzymic Modification", Endocrinology, Vol. 101, No. 5, pages 1587-1603, 1977.   |          |   |                       |   |                               |
|  | AT | Urban J. LEWIS et al., "A naturally occurring structural variant of human growth hormone", The Journal of Biological Chemistry, Vol. 253, No. 8, pages 2679-2687, 1978.   |          |   |                       |   |                               |
|  | AU | U. J. LEWIS et al., "Human growth hormone: Additional members of the complex", Endocrinology, Vol. 104, No. 5, pages 1256-1265, 1979.   |          |   |                       |   |                               |
|  | AV | U. J. LEWIS et al., "The 20,000-Dalton Variant of Human Growth Hormone: Location of the Amino Acid Deletions", Biochemical and Biophysical Research Communications, Vol. 92, No. 2, pages 511-516, January 29, 1980.            |          |   |                       |   |                               |
|  | AW | Urban J. LEWIS et al., "Altered Proteolytic Cleavage of Human Growth Hormone as a Result of Desamidation", The Journal of Biological Chemistry, Vol. 256, No. 22, pages 11645-11650, 1981.                                      |          |   |                       |   |                               |
| Examiner /Stephen Gucker/  |    |   |          | Date Considered 04/13/2009              |                       |   |                               |
| *Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |    |   |          |   |                       |   |                               |

|  |     |   |  |   |  |  |  |
|--|-----|---|--|---|--|--|--|
| Form PTO 1449<br>(Modified)  |     | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE  |  | ATTY DOCKET NO.<br><br>277219US0PCT         |  | 1001-1002<br>SERIAL NO. 19763<br>New U.S. PCT Application<br>Based on PCT/EP04/50286 |  |
| LIST OF REFERENCES CITED BY APPLICANT  |     |   |  | APPLICANT<br><br>Piergiorgio DONATI, et al. |  |  |  |
|  |     |   |  | FILING DATE<br><br>Herewith                 |  | GROUP  |  |
| OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)  |     |   |  |   |  |  |  |
|  | AX  | MARTIAL et al., "Human Growth Hormone: Complementary DNA Cloning and Expression in Bacteria" Science, Vol. 205, pages 602-607, 1979.  |  |   |  |  |  |
|  | AY  | Judy MEINKOTH, Geoffrey WAHL: "Hybridization of Nucleic Acids Immobilized on Solid Supports", Analytical Biochemistry, Vol. 138, No. 2, pages 267-284, May 1, 1984.   |  |   |  |  |  |
|  | AZ  | Jerome A. MOORE et al., "Equivalent Potency and Pharmacokinetics of Recombinant Human Growth Hormones with or without an N-Terminal Methionine", Endocrinology, Vol. 122, No. 6, pages 2920-2926, 1988.   |  |   |  |  |  |
|  | AAA | William R. PEARSON: "Rapid and Sensitive Sequence Comparison with FATP and FASTA", Methods in Enzymology, Vol. 183, pages 63-98, 1990.  |  |   |  |  |  |
|  | AAB | William R. PEARSON and David J. LIPMAN: "Improved tools for biological sequence comparison", Proc. Natl. Acad. Sci., Vol. 85, pages 2444-2448, April 1988.  |  |   |  |  |  |
|  | AAC | R. PEARLMAN and T. H. NGUYEN: "Formulation Strategies for Recombinant Proteins: Human Growth Hormone and Tissue Plasminogen Activator, Therapeutic Peptides and Proteins, Formulations, Delivery and Targeting, Current Communications in Molecular Biology, pages 23-30, 1989. |  |   |  |  |  |
|  | AAD | R. N. P. SINGH et al., "Modified Forms of Human Growth Hormone with Increased Biological Activities", Endocrinology, Vol. 94, No. 3, pages 883-891, 1974.   |  |   |  |  |  |
|  | AAE | Roy G. SMITH et al., "A Nonpeptidyl Growth Hormone Secretagogue", Science, Vol. 260, pages 1840-1843, June 11, 1993.  |  |   |  |  |  |
|  | AAF | SMITH and WATERMAN: "Identification of Common Molecular Subsequences", J. Mol. Biol., Vol. 147, pages 195-197, 1981. "Comparison of Biosequences", Advances in Applied Mathematics, Vol. 2, pages 482-489, 1981.  |  |   |  |  |  |
|  | AAG | Ole THORLACIUS-USSING: "Zinc in the Anterior Pituitary of Rat: A Histochemical and Analytical Work", Neuroendocrinology, Vol. 45, pages 233-242, 1987.  |  |   |  |  |  |
|  | AAH |   |  |   |  |  |  |
|  | AAI |   |  |   |  |  |  |
|  | AAJ |   |  |   |  |  |  |
|  | AAK |   |  |   |  |  |  |
|  | AAL |   |  |   |  |  |  |
|  | AAM |   |  |   |  |  |  |
|  | AAN |   |  |   |  |  |  |
| Examiner /Stephen Gucker/  |     |   |  |   |  | Date Considered 04/13/2009   |  |
| *Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |     |   |  |   |  |  |  |

10/5497 63

JP 00 360 PCT/PTO 19 SEP 2005

New U.S. PCT Application Based on PCT/EP04/50286  
Docket No.: 277219US0PCT

STATEMENT OF RELEVANCY

- 1) References AA, AB and AC have been cited in the International Search Report. Copies of these references are being submitted herewith only when not automatically provided by the International Searching Authority.
- 2) Reference      have been cited in the corresponding          Search Report. A copy of this reference is being submitted herewith.
- 3) References AD-AAG are discussed in the specification. A copy of these references is being submitted here with.
- 4) Reference      is additional prior art known to Applicant. A copy of these references is being submitted herewith.